Group III: Claims 16-21, drawn to methods of preventing infection, classified in class 424, subclass 204.1.

Group IV: Claims 22-27, drawn to methods of treating an existing infection, classified in class 424, subclass 204.1.

In addition, with respect to Groups III and IV, the Examiner is requiring election of a pathogen from the list including bacteria, virus mycoplasma, yeast or parasite. If virus is elected, then the Examiner is requiring a further election from the list including HIV, RSV, flu virus and cold virus.

A. Applicants' Election & Traversal

In response, applicants elect Group I with traverse for prosecution at this time. In addition, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement.

B. The Legal Standard for Restriction Has Not Been Met

35 U.S.C. §121 provides that "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." M.P.E.P. §802.01 deviates from the plain meaning of "independent and distinct" by interpreting "and" to mean "or". The Patent Office relies on the absence from the legislative history of anything contrary to this interpretation as support for their position that "and" means "or". Applicants respectfully note that this position is contrary to the rules of statutory construction. Restriction between two dependent inventions is not permissible under the plain meaning of 35 U.S.C. §121.

The Examiner does not assert that the inventions of Groups I-IV above are independent. Rather, the Examiner alleges that the inventions of Groups I-IV are distinct because they are directed to process of making and product made (Groups I and II); product and process of use (Groups II and III/IV); differing target populations and end results (Groups III and IV); and differing methods steps resulting in differing outcomes (Groups I and III/IV). Applicants assert that, because the products and methods of the invention depend on each other, restriction between

these dependent inventions is improper. Moreover, the claimed products and methods are all defined by the same method of producing a secretory immunoglobulin in a single cell.

C. The Subject Matter of Claims 1-27 is Linked by a Common Inventive Concept

Applicants further request that the Examiner take into consideration that each of the methods encompassed by Groups I, III and IV, and the products of Group II involves secretory immunoglobulin produced by a novel method. The ability to efficiently produce secretory immunoglobulin in a single cell is an inventive concept underlying each of claims 1-27.

With respect to Groups I and II, the Examiner's statement that the secretory antibodies can be isolated from non-recombinant hybridomas expressing them (Office Action at 2) is erroneous. The Examiner is respectfully requested to note page 2 of the specification, line 5, to page 3, line 13, which describes the state of the art relevant to this invention. In particular, page 2, lines 16-19, point out that IgA antibodies produced by hybridomas (not the same as secretory IgA) are rapidly degraded. Lines 23-26 of page 2 further note the inability to produce sufficient quantities of sIgA using co-culture systems. Prior to Applicants' invention, there was no method for producing sIg as claimed in a single cell. Moreover, the products of Group II are defined as being made by the process of Group I, and thus it is illogical to state that these products can be made by an alternate method.

D. No Serious Burden Is Placed on the Examiner

According to M.P.E.P. §803, there are two criteria for a proper restriction requirement. First, the two inventions must be independent and distinct. In addition, there must be a serious burden on the Examiner if restriction is not required. Even if the first criterion has been met in the present case, which it has not, the second criterion has not been met.

The Examiner asserts that restriction is proper because the inventions have acquired a separate status in the art due to their different classifications (Office Action at 3). Applicants note, however, that the Examiner has identified only two separate classes and three separate subclasses for the 4 allegedly distinct inventions (Group I in class 435, subclass 70.21; Group II in class 424, subclass 147.1; and Groups III & IV in class 424, subclass 204.1). Even if restriction is supported by a showing of separate classifications, such a *prima facie* showing by the Examiner of a serious